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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

THOMPSON, MICHAEL M

ART UNIT PAPER NUMBER

3763

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/851,372

Applicant(s)

FORMAN, MICHAEL R.

Examiner

Michael M. Thompson

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4, 18 and 22-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 5-21 is/are rejected. <sup>5-17, 17-21</sup>
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 6, 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 3-4, 18, and 22-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

### ***Specification***

2. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as the term "means" Correction is required. See MPEP § 608.01(b).

### ***Claim Objections***

3. Claims 19 and 21 are objected to because of the following informalities: Claim 19 refers to a non-elected claim. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 5, and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Racchini (392). The patent to Racchini discloses the recited combined radiation and radiosensitizer delivery catheter comprising a catheter body 14, an ionizing radiation source 28 that is located within an area 22 which is an inflatable balloon for releasing a radiosensitizer through the microporous balloon 22 to treat a lumen in the body. The radiosensitizer can be used

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to expand the balloon, a method of using the apparatus is given, and the entire apparatus is considered to be inherently a kit and that inherently any apparatus would come with instructions for its use.

6. Claims 1, 5, and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Shapland. The patent to Shapland discloses the recited combined radiation and radiosensitizer delivery catheter comprising a catheter body 14, an ionizing radiation source 28 that is located within an area 22 which is an inflatable balloon for releasing an radiosensitizer through the microporous balloon 22 to treat a lumen in the body, where the radiosensitizer can be used to expand the balloon, a method of using the apparatus is given, and the entire apparatus is considered to be inherently a kit and that inherently any apparatus would come with instructions for its use. Another embodiment discloses in figure 7 a two-balloon system where the radiosensitizer is provided through a tube 39 to a space between the two balloons.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 5-6, 11-16, 18, and 28 are rejected under 35 USC. 103(a) as being unpatentable over Shapland or Racchini (392) in view of Leone or Winkler ('257). The patents to Shapland and Racchini disclose all of the recited structure with the exception of providing the radiosensitizer in a releasing matrix. The patent to Leone discloses the recited infusion balloon

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catheter that can be provided with a matrix over the balloon to control release of a chemical into the lumen in a body. Similarly, Winkler discloses a catheter with a hydrogel membrane matrix with radiosensitizers as set forth in claims 5 and 6. It would have been obvious to one skilled in the art to modify the balloons in Shapland or Racchini by providing a matrix around the balloon to more precisely control the release of chemicals into the body as suggested by Leone or Winkler.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shapland or Racchini. The patents to Shapland and Racchini disclose all of the recited structure with the exception of using radioisotopes for radiation source and encapsulating the radiosensitizers. It is considered old and well known to use radioisotopes and encapsulating chemicals to control their release, it would have been obvious to one skilled in the art to modify the source of radiation in Shapland or Racchini by substituting radioisotopes for the radiation source and to encapsulate the radiosensitizer as such is old and well known in the art to control the release of chemicals.

10. Claims 2, 19-20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapland or Racchini (392) in view of Forman. The patents to Shapland and Racchini disclose all of the recited structure with the exception of forming the radiation source as an x-ray source and providing perfusion thread on the balloons. The patent to Forman discloses the recited infusion balloon catheter which can be provided with a perfusion thread 19 over the balloon 18 to control release of a radiation into the lumen in a body and a radiation source 22 which can include an x-ray tube. It would have been obvious to one skilled in the art to modify the balloons

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in Shapland or Racchini by providing a perfusion thread around the balloon in any manner to more precisely control the release of radiation into the body and to use an x-ray tube for the source of radiation as suggested by Forman as such would be useable in different situations.

### Contacts

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Michael Thompson whose telephone number is (703) 305-1619. The Examiner can normally be reached on Monday through Friday from 9 am to 5 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Primary, AnhTuan Nguyen, can be reached on (703) 308-2154. The official fax phone number for submissions to the organization where this application or proceeding is assigned is (703) 872-9302. The official fax phone number for submission of After Final response is (703) 872-9303.

Michael M. Thompson

Patent Examiner

MT 

January 13, 2003



MICHAEL J. HAYES  
PRIMARY EXAMINER